

contamination by poxviruses and by all human plasma constituents, and (4) has a specific activity defined as the ratio:

Concentration of test sample required to clot a given volume of factor IX-deficient plasma in a given time by the kaolin-cephalin method

Concentration of factor IX protein in the test sample as determined by ELISA

of at least 90% of that of average normal human plasma used as a standard and set at 100%.

22. Factor IX protein according to claim 21 having a specific activity of 100%.

23. A method of treating a human patient suffering from a deficiency of factor IX, said method comprising the step of administering to the patient a biologically active recombinant DNA-derived factor IX protein which (1) is the product of expression of cDNA encoding factor IX from a single allelic form, (2) has an amino acid sequence of human factor IX protein or of a protein retaining the monomorphism of the cDNA allele and sufficiently similar thereto to make it acceptable for infusion into human patients suffering from factor IX deficiency, (3) is free from contamination by poxviruses and by all human plasma constituents, and (4) has a specific activity defined as the ratio:

Concentration of test sample required to clot a given
volume of factor IX-deficient plasma in a given time by the
kaolin-cephalin method

Concentration of factor IX protein in the test sample as
determined by ELISA

of at least 90% of that of average normal human plasma used as a
standard and set at 100%.

24. A method according to claim 23, wherein the factor IX
protein has a specific activity of 100%.--